TALC ALTERNATIVES

RESEARCH PROPOSAL

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BACKGROUND

During the past couple years our need for a non-talc dusting powder base has increased as a direct result of the talc/asbestos controversy. The thrust against talc has centered primarily on biological problems alleged to result from the inhalation of talc and related mineral particles.

For defensive reasons, in the event that talc must be removed from the market, the development of a product based on ordinary cornstarch (Formula 31) is being finalized. The product concept is that Formula 31 is divorced from talc allegations, since cornstarch is a non-mineral. The assumption is that Formula 31 will be non-reactive (i.e. biodegradable) if inhaled as well as being digestible if ingested. However, inhalation studies on a scale necessary to establish non-reactivity have not been conducted.

A product compounded from ordinary cornstarch gives us no business exclusivity; moreover we must be prepared for a less than enthusiastic consumer response as regards aesthetic qualities such as lubricity and perfume bloom. Our opinion is that those qualities in the cornstarch product are inferior to those in talc.

Consequently, the ideal objective is the development of a non-talc biodegradable powder base, with performance

characteristics comparable to talc, and superior to the ordinary cornstarch products developed to date.

This report proposes some technical routes which can lead to that objective.

MEDICAL AND BIOLOGICAL REQUIREMENTS

Our 80 year leadership in the infant dusting powder market has been maintained largely because of incomparably strong merchandising of a product which is aesthetically superior. That superiority has hinged on our use of very high grade talc compounded with an exclusive perfume.

In the light of present day emphasis on product safety, it becomes essential that we strengthen our medical and biological understanding of the performance characteristics of body powders. This information should be collated with our understanding of the chemical and physical properties of any dusting powder material which is applied topically to the body. Such investigation should proceed concurrently with our search for new materials so that we do not emphasize aesthetics at the expense of function.

Specifically we should research and quantify what particular qualities of powders give the perception of cooling comfort, in hot weather, which factors relate to skin anchorage of powders to different areas of the body, and what components and variables in urine, perspiration, and other body exudates have affinity or repellancy to powder particles.

We must also acquire medical clarification as to the nature of particle travel in the respiratory tract, and particularly how biological and sensory factors control or regulate the disposition of inhaled particles.

The accumulation of the above knowledge will enable us to single out and pursue the specific factors whichdshould be sought in the development of an ideal powder base.

Without the above medical and biological research, introduction of any new powder product can be no more than a good gamble since we shall still not know or be able to explain exactly how a body powder works and/or our justification for marketing a new product.

In order to implement the above avenues of investigation, it will be necessary to draw on the services of several areas of expertise within the Baby Products Company Research & Development staff as well as from others within the Johnson & Johnson structure both here and abroad. The acquisition of such material must be organized in such a way that there are no barriers to obtaining or providing pertinent sensitive information.

RECOMMENDED TECHNICAL APPROACHES

It is appropriate to divide the search for an ideal powder base into two routes of technology; viz;-

PART I - BIOGRADABLE ....
those materials which presently available information or experience indicate are biodegradable at the body tissue level and which lend themselves to powder forms.

A. STARCHES

B. GUMS & RELATED MATERIALS

PART II - INERT ....
materials which are likely to be tolerated by the body (histocompatible) but are not necessarily biodegradable.

The following technical routes are presented in the order of priority in which they should be investigated taking into account chemical and process latitudes and potential availability in large quantities.

PART I

BIODEGRADABLE MATERIALS

A. STARCHES

The starch family of materials warrant the major initial emphasis because many varieties are well known to be digestible if ingested and in some cases are known to be biodegradable and assimilated by the body when implanted in live tissue.

It is advisable to acquire and categorize all natural starches which can be commercially available, to ascertain whether cornstarch is (or is not) the most preferred starch base. As regards to particle size related to inhalation, present trend of thinking on talc indicates a respirable cut-off at about five microns, aerodynamically, The natural starches are available over wide ranges of particle size and shape from low micron rice starches (1 micron) to very large (100 microns) globular potato and sago starches.

Cornstarches normally run in the middle (25 microns) of the natural starch particle size range. It is therefore unlikely that cornstarch will be our best material from strictly the raw material size/shape point of view. The categorizing of the size/shape consist,

collated with readily perceived properties of slip, purity, moisture affinity and the like, will be valuable in initiating applied research on any other starches. Such categorizing will be useful both for product development and possible patent protection purposes.

There are not only many different starches but many varieties of each starch and many derivitives of each variety. The different starch materials will have different surface properties and different modes of activity in and on the body.

In order to discover the best starch product for our use it is advisable to conduct the above natural starch screening effort concurrently with an intensified examination of product possibilities across the board of cornstarch technology. This should be conducted not merely because a desirable cornstarch product variant can eventuate, but because the technology acquired during such examinations can be readily translated into any of the other natural starches which might be elicited in the above raw starch screening work.

The facts of cornstarch chemistry permit the following plan for maximum benefit:

1. Cornstarch can be fractionated into its two molecular structures; the one being linear and the other being branched chained molecules. The two basic structures should be inplanted in animals to determine any biodegradable advantage of either one over the other compared to the parent cornstarch. If successful, this will give us a beneficiated starch fraction as a base line of reference.

2. The various starch derivatives resulting from chemically modifying the surface of cornstarch should be categorized for improvements in skin anchorage, textural improvements or esthetic indications, compared to the unmodified cornstarch from which they were synthesized. This will tell us which chemically altered modification of starch has properties we seek.

3. The derivative which is selected from (2) should then be prepared from the fraction which is preferred from (1). This will give us a surface treated fraction of cornstarch with product properties better than raw cornstarch, based on an established superior fraction at the biodegradable tissue level.

4. If the above plan works out successfully, then the findings developed on cornstarch can be translated or applied to the best raw starch (e.g. potato, sago, tapioca, etc.) which will result from the initial screening of raw starch types above. This will give us the best derivative of the best fraction of the best basic starch.

In regards to implementation of the above starch research, it will be essential that we work with some knowledgeable starch house under a tight agreement.

B. GUMS AND RELATED MATERIALS

One group of materials which has highly developed and recognized physiological acceptance is the blood plasma extenders. The technology required to synthesize and manufacture such sophisticated materials in medical grades accounts for their elevated price. However, it is precisely because of their elegance and cost that there may be powder opportunities in the group. It is conceivable that lower cost, technical or industrial grades of those materials can be made available which would more than meeti our biological requirements as a powder base or powder component.

In order to decide what emphasis such materials should receive, the first step will be to acquire a medical listing of the plasma extenders which have been manufactured or suggested on a world basis.

Such materials will then be reviewed for possible powder varieties (less than medical grade), and a technical decision reached to look seriously into any which have promise. Promising materials in the above group will include not only any which can be made into a powder, but also those materials which can be used as a powder additive or surface coating on another powder base, (e.g. starch), to impart a positive biological factor to the base material.

Another group of materials, where we know physiologically sound materials exist, include some carbohydrates (cellulosics and gums) and some synthetic polymers (e.g. methacrylates). We should acquire an updated review of the possibilities with that group, particularly those which can be available in large tonnage and are capable of pharmaceutical elegance. For example, some of the pectic substances have been produced (from oranges) in powder form, and it is logical to expect that they can be chemically and physically altered to our advantage in ways similar to the foregoing starch plan.

PART II

INERT MATERIALS

There are two overriding facts which require attention on inert materials in the present search for a talc alternative. The first is that we may not be fully successful in acheiving the development of the preferred ideal biodegradable powder base and may have to resort to a compromise material such as an inert base. The second is that we know that competition in both the talc and body powder industry is looking into possible inert base materials, and we cannot afford to be caught by a competitive threat unaware.

The chemical industry has called a variety of materials to the attention of several talc consumers during the past few years, hoping to spark some serious interest. Those materials are primarily in the organic polymer class, and as such can be prepared in a variety of physical forms at the particle level. For example, there have been attempts to arouse interest in powders of polyethylene, teflon, nylon, dacron, microcrystalline cellulose and powdered kapok. At times, some rather novel particle spectrums of those materials have been circulated around the trade. For example, solid microspheres of saran and

polystyrene have been available in laboratory curiosity amounts, here in the States. Overseas there was a suggestion of pharmaceutical interest in a crushed urea-formaldehyde foam specifically aimed at a body powder possibility.

As far as we now know, none of the above items has ever gained any real momentum of interest, primarily because the industry considered the projected costs too high to be of anything but academic interest.

However, the chemical industry is now aware of the present talc climate and a focus on potentially novel materials can be expected.

This entire area is one which requires our careful review. At the present time, our knowledge of the state of the art is not good enough to make a reliable judgement of real body powder potential of such materials. However, it is advisable that we start to look for leads within that category of materials, so we can recommend solid direction and recognize any opportunities which eventuate.